DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 31, 2015

NIBEC CO., LTD
c/o Mr. Daniel Nam
PATS CORP
904 E. Windsor Road #102
Glendale, CA 91203

Re: K142040
Trade/Device Name: OCS-B Collagen®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: June 30, 2015
Received: July 2, 2015

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142040

Device Name

OCS-B Collagen®

Indications for Use *(Describe)*
OCS-B Collagen ® is recommended for:
- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K142040
510(k) Summary

Sponsor/Applicant

NIBEC Co., Ltd.
Iwol electricity-electronic Agro-industrial Complex,
116, Bamdi-gil, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea
Phone: 82-10-2889-8590
Fax: 82-2-744-8732
Contact: Dr. Park, Yoon-Jeong

Date Prepared : July 29, 2015

Device Name and Identification

Proprietary Name:	OCS-B Collagen®
Common/Usual Name:	Bone Grafting Material Plus Collagen
Anorganic Bovine Bone Grafting Material	
Classification Name:	Bone Filling Material
Bone grafting material, animal source (NPM)	

Predicate devices

Bio-Oss Collagen® (K092428)
(Primary Predicate)
Manufactured by:
Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

OCS-B® (K113246)
(Reference Predicate)
Manufactured by:
NIBEC Co., Ltd.
Iwol electricity-electronic Agro-industrial Complex,
116, Bamdi-gil, Iwol-myeon, Jincheon-gun,
Chungcheongbuk-do,
Korea

Device Category/Class

Device Class:	Class II
Regulation Number:	21 C.F.R. 872.3930
Product Code:	NPM

Intended use

OCS-B Collagen® is recommended for:
Filling of large oral and maxillofacial intra-osseous cavities

Indications for use

OCS-B Collagen® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

Device Description

OCS-B Collagen® is a combination of purified cancellous bone mineral granules (OCS-B®) and 10% collagen in a block form in a blister and cylinderic form in a syringe and blister. It is sterilized by γ-irradiation.

Basis for Substantial Equivalence

OCS-B Collagen® and Bio-Oss® Collagen have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the osteoblast. Both products have same component ratio of bone mineral granules and collagen. Both products have same source of bone (bovine bone), and collagen (porcine skin). The bone granules were treated through a specific process for removal of organic compound. The collagen was purified through specific process for removal of other proteins and organic compounds. Therefore, OCS-B Collagen® is substantially equivalent to Bio-Oss® Collagen.

The following is a table comparing OCS-B Collagen®, Bio-Oss Collagen® and OCS-B® a Bone graft cleared for GBR.

Table 1: Substantial Equivalence Comparison

<table>
<tr><th>ITEM</th><th>OCS-B Collagen®</th><th>Primary Predicate
Bio-Oss® Collagen*
(K092428)</th><th>Reference Predicate
OCS-B®**
(K113246)</th></tr>
<tr><td>Intended Use</td><td>Used as an adjective therapy in restoring bony defects</td><td>Used as an adjective therapy in restoring bony defects</td><td>Used as an adjective therapy in restoring bony defects</td></tr>
<tr><td>Target population</td><td>Human oral, periodontal</td><td>Human oral, periodontal</td><td>Human oral, periodontal</td></tr>
<tr><td>Dosage form</td><td>a block form in a blister
a cylinderic form in a syringe and blister</td><td>a block form in a blister</td><td>Granules contained in single use container</td></tr>
<tr><td>Dimension</td><td>0.2mm to 1.0mm or 1.0mm to 2.0mm granules
<table><tr><th>Shape</th><th>Dimension (mm)</th><th>Weight (g)</th></tr><tr><td>Block</td><td>6X6X3</td><td>50mg</td></tr><tr><td>Block</td><td>6X6X6</td><td>100mg</td></tr><tr><td>Block</td><td>7X8X9</td><td>250mg</td></tr><tr><td>Block</td><td>9X10X11</td><td>500mg</td></tr><tr><td>Cylinderic</td><td>4.6X40</td><td>250mg</td></tr></table></td><td>0.25mm to 1.0mm or 1.0mm to 2.0mm granules
<table><tr><th>Shape</th><th>Dimension (mm)</th><th>Weight (g)</th></tr><tr><td>Block</td><td>6X6X6</td><td>100mg</td></tr><tr><td>Block</td><td>7X8X9</td><td>250mg</td></tr><tr><td>Block</td><td>9X10X11</td><td>500mg</td></tr></table></td><td>0.2mm to 1.0mm or 1.0mm to 2.0mm granules</td></tr>
</table>

= Primary Predicate (K092428)* *=Reference Predicate(K113246)*

	Cylinderic 5.6X45 500mg		
Material	Anorganic derived osteoconductive hydroxyapatite (pre-sterilized product of OCS-B® (K113246), Collagen	Anorganic derived osteoconductive hydroxyapatite, Collagen	Anorganic derived osteoconductive hydroxyapatite bone mineral
Source of bone	Bovine bone	Bovine bone	Bovine bone
Source of collagen	Porcine skin	Porcine skin	-
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatible	Biocompatible, as demonstrated by : - Cytotoxicity testing - Hemolysis testing - Acute systemic injection testing - Intracutaneous reactivity testing - Skin sensitization testing (LLNA) - Genotoxicity testing (Micronucleus test) - Oral Mucosa Irritation - Genotoxicity testing (AMES test) - Implantation testing - Genotoxicity testing(Chromosome aberration test) - Preclinical quality testing - Clinical case series	Biocompatible (as demonstrated in published literature)	Biocompatible (as demonstrated in published literature)
Performance	Bone formation	Bone formation	Bone formation
Compatibility with other devices	Can be used with GTR membrane	Can be used with GTR membrane	Can be used with GTR membrane

Sterilization Process	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation
Biocom-patibility	Biocompatible	Biocompatible	Biocompatible
Anatomical sites	Oral, Periodontal	Oral, Periodontal	Oral, Periodontal
Non-Pyrogenic	Yes	Yes	Yes
Shelf-Life	36 Months	36 Months	36 Months

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of OCS-B Collagen® and Bio-Oss® Collagen with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of OCS-B Collagen® resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement.

OCS-B Collagen® was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Devices" and in accordance with ISO 10993. Test results confirmed equivalence to predicates. OCS-B® (K113246) was manufactured to remove organic impurities and product specifications have been established to limit protein content. Throughout the risk analysis for each production step, for example, cleaning validation, the removal of organic solvent, the risk control was conducted during the manufacturing process. In addition, the TSE inactivation validation as well as virus inactivation study result confirmed product suitability. Collagen is purified from porcine skin by a standardized controlled manufacturing process. The type I collagen has been purified from veterinary certified porcine skin. OCS-B Collagen® is composed of cancellous bone mineral granules (pre-sterilized OCS-B®) and 10% collagen. The dosage form is a block form in a blister or a cylinderic form in a syringe and blister. Further, the product is sterilized to achieve a sterility assurance level SAL 1 x 10^{-6}. Further, OCS-B Collagen® is sterilized to achieve a sterility assurance level SAL 1 x 10^{-6}.

Specifically, OCS-B Collagen® was evaluated and tested in accordance with the following performance standards:

- ISO 10993 "Biological Evaluation of Medical Devices"
- ASTM F 1581-99 "Standard Specification for Composition of Anorganic Bone for Surgical Implants" (1999)
- FDA's "Medical Device Materials Derived from Animal Sources" (1998)
- ISO 11137 "Sterilization of Healthcare Products – Radiation"
- ASTM F 1980-99 "Standard Guide for Accelerated Aging of Sterile Medical device Packages"

Based on the information presented herein, it has been demonstrated that OCS-B Collagen® is substantially equivalent to Bio-Oss® Collagen, and suitable for the proposed indications for use.

Conclusion

OCS-B Collagen® has the same indications for use, same intended use, same sterilization process, same shelf-life, biocompatibility and similar technologies as its primary predicate, Bio-Oss® Collagen. The subject device and predicate device encompass the same range of physical dimensions. They share similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the osteoblast. Both products have same component ratio of bone mineral granules and collagen.

Both products have same source of bone (bovine bone), and collagen (porcine skin). The bone granules were treated through specific process for removal of organic compound. The collagen was purified through specific process for removal of other proteins and organic compounds.

OCS-B Collagen® presents the same types of potential risks to consumers as the predicate device Bio-Oss® Collagen, and has controlled these risks in a similar manner. Accordingly, OCS-B Collagen® is deemed suitable for its intended uses. Biocompatibility tests and additional performance testing demonstrate that OCS-B Collagen® meets the requirements of those standards.

The nonclinical, animal and clinical data included in this submission support the substantial equivalence of OCS-B Collagen® to the predicate devices listed in this submission. Literature and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specifications and performance. Therefore, it is concluded that OCS-B Collagen® is substantially equivalent to the predicate device.